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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,833	07/01/2003	Mark Deem	020979-000510US	3863

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TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER

GHERBI, SUZETTE JAIME J

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 01/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Tata

Office Action Summary

Application No.

10/612,833

Applicant(s)

DEEM ET AL.

Examiner

Suzette J. Gherbi

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 16-28 and 37-39 is/are pending in the application.
- 4a) Of the above claim(s) 8-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 16-28 and 37-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendment dated 7/13/05 and response dated 11/3/05 have been received in application serial number 10/612,833. All comments have been taken into careful consideration.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-7, and 16-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In particular claim 1 states "...agent inhibits...". Applicant's specification only recites that the agent "*slows the dilation*" (see [0008]). The specification does state that agents can inhibit bacterial infection, but does not mention inhibiting dilation and weakening of the wall of the aorta.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-7, 16-28, 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ouriel et al 2004/0117003 in view of Hoffman Jr. et al. 5,197,977. Ouriel et al. discloses the invention as claimed noting figures 1-13 comprising: A method for treating an aneurysm by "*directing*" at least one therapeutic agent "*outwardly to*" at a location "*on an aortic wall*" near the aneurysm, "*wherein the therapeutic agent inhibits dilation and weakening of the wall of the aorta*"; wherein the agent is releasably carried by at least one device (see [0123]); wherein the device has at least one stent member for engaging a portion of a blood vessel in which the aneurysm is located (44); wherein the device has a tubular member coupled with the stent member (30); wherein the device also has a first stent member for anchoring (46) the device and a skirt member; the skirt member having a proximal end (40) and a distal end (16 converging area) the skirt member extending from the stent in a direction towards the aneurysm; wherein the device also has a second stent member coupled with the first stent member (42, 48). However Ouriel et al. does not limit the type of drugs that can be associated with the device. Hoffman, Jr. et al. teaches a bifurcated graft that

incorporates the use of collagen fixed to the graft substrate in combination with the use of antibacterial agents such as tetracycline capable of slowing dilation (see col. 5, lines 59-70 and col. 6, lines 13). It would have been obvious to one having ordinary skill in the art at the time the invention was made to take the invention of Ouriel et al. and incorporate collagen and tetracycline as taught by Hoffman, Jr. et al. because both devices are bifurcated, polymer based grafts used for the treatment of aneurysms and both polymers and devices are capable of carrying such agents. Also it is obvious that because the entire device of Ouriel et al. is disclosed as be coated on the external surface that this would also include the skirt, which extends from the "anchor" (stent).

Response to Arguments

4. Applicant's arguments filed 7/13/05 have been fully considered but they are not persuasive. Applicant has amended the claims and contends that Ouriel '003 does not describe delivery a therapeutic agent to an aneurysm. The examiner disagrees. In section [0012] Ouriel discloses that the invention can be used to treat abdominal aortic aneurysm. Section [0123] discloses that agents can be associated either with the inside or the outside of the device. It is obvious if not inherent that if drugs/agent are supplied on the outer surface of the device and implanted in the location of an aortic aneurysm that is in fact delivering n agent to an aneurysm. The new limitation of "inhibiting" dilation are not supported by the applicants specification as rejected above.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the suggestion or motivation to modify the teachings arise from the fact that both Ouriela and Hoffman have grafts made from Dacon and it is obvious that any number of therapeutics including antibiotics are capable of being incorporated into the graft of Ouriel. As previously mentioned Ouriel's implant is implanted in the area of an aortic aneurysm and therefore the drugs perform the functions as claimed to the wall of the aorta.

Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within


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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzette J. Jackson whose work schedule is Monday-Friday 9-6:30 off every other Friday and whose telephone number is 571-272-4751.

7. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306.

8. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.


Suzette J-J Gherbi
10 January 2006